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6th Annual

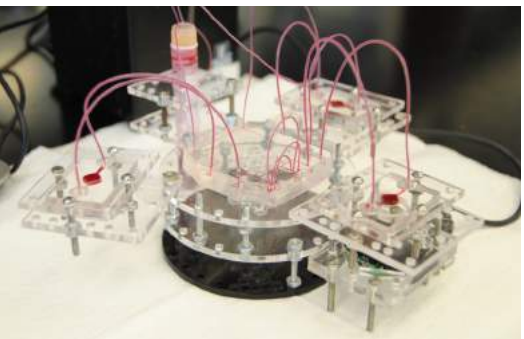
Regenerative Medicine Essentials:

From the Fundamentals to the Future

June 10–14, 2019

Wake Forest Bowman Gray Center for
Medical Education, Winston-Salem NC

Official Course of REGENERATIVE MEDICINE FOUNDATION



Welcome to Regenerative Medicine Essentials 2019

On behalf of the course organizing committee and our prominent group of course instructors, we welcome all of you to the 6th Annual *Regenerative Medicine Essentials: From the Fundamentals to the Future* course.

Often referred to as the next evolution of modern health care, the regenerative medicine field touches many disciplines -- from clinical care and engineering to basic science and bioethics. This one-week course, the "official course of the Regenerative Medicine Foundation", taught by leading experts in the field, addresses the multidisciplinary nature of regenerative medicine and provides attendees a firm foundation in this exciting field, insight into current state of the field encompassing applications and challenges as well as a glance to the future.

In partnership with the Regenerative Medicine Foundation, the organizing committee has put together a dynamic and informative course that covers the "essential" topics and fundamental principles and current progress in tissue engineering and regenerative medicine, including stem cells and cell therapy, biomaterials, technology-based tissue engineering and enabling technologies, as well as regulatory, ethical, economic issues critical to the field. We are also excited to offer a new session, Regenerative Rehabilitation, held in partnership with the Alliance for Regenerative Rehabilitation Research and Training.
We also offer three *Into the Lab* pre- and post- course workshops. These workshops provide hands-on interaction and demonstrations with cutting-edge technologies and techniques for regenerative medicine applications. Participants will have an opportunity to review and interact directly with these technologies and leading researchers at WFIRM. Workshops are also designed to provide translational and commercial insight regarding these technologies and will highlight some of the current challenges along with potential approaches to overcome technical hurdles.

Our instructors, which include faculty from the Wake Forest Institute for Regenerative Medicine as well as distinguished, prominent experts in the field from industry, academia and the government who join us from across the globe, provide attendees a strong foundation along with insights into future directions and potential applications of tissue engineering and regenerative medicine. Further, the 1-week course is a dynamic event, providing an ideal setting for academic, clinical, industry and government professionals to network with colleagues, encouraging formation of new exchanges, collaborations and learning opportunities.

We hope the 6th Annual Regenerative Medicine Essentials course will further interactions among basic scientists engaged in discovery and development, translational researchers who bring laboratory discoveries to the clinical forefront, clinicians and those engaged with funding, regulatory and commercialization endeavors.

We look forward to an exciting, enjoyable and productive course for all.

Anthony Atala, MD
Director, WFIRM
RME 2019 Course Director

Joan F. Schanck, MPA
Head of Education, WFIRM
RME 2019 Course Co-Director

Welcome to Regenerative Medicine Essentials 2019

On behalf of the Regenerative Medicine Foundation (RMF), I welcome you to RMF's "official course"— the 5th annual R*egenerative Medicine Essentials: From the Fundamentals to the Future*. We believe the course is a perfect platform for advancing the RMF mission to accelerate regenerative medicine to improve health and deliver cures.

Here at RMF, we recognize that the power of collaboration grows in a nonlinear fashion. One plus one is more than two, and one plus one plus one is much, much more than three — offering explosively positive and unpredictable possibilities. By attending this course, you will expand your knowledge in a totally immersive experience and gain personal connections and collaborations. Be open to all opportunities presented.

Interact with the outstanding interdisciplinary faculty and the superlative researchers of our host institution, the Wake Forest Institute for Regenerative Medicine, led by our treasured friend, Dr. Anthony Atala. We are here for you. Open to your questions and points of view.

This week I urge you to network with fellow attendees. Break bread, make new friends and remember to collect those opportunities.

In my journey, I have found Winston-Salem to be one of the most collegial places on the planet. This week, I assure you, it's the best place to learn about the future of medicine!

Cordially,

Bernard Siegel, JD
Executive Director, Regenerative Medicine Foundation
Founder & Chair, World Stem Cell Summit

REGENERATIVE
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FOUNDATION

With Special Thanks and Recognition

Organizing Committee

Anthony Atala, MD
RME 2019 Course Director;
Director, WFIRM

Bernard Siegel, JD
RME 2019 Course Co-Director;
Executive Director, Regenerative Medicine Foundation

Joan F. Schanck, MPA
RME 2019 Course Co-Director;
Head of Education, WFIRM

Joanne Gray
Education and Outreach Coordinator, WFIRM

Bonnie Davis
Communications Manager, WFIRM

Taylor Dickerson
RME 2019 Program Coordinator, WFIRM

Workshop Leaders and Committees

Introduction to Translation
Julie Allickson, PhD
Director, Regenerative Medicine Clinical Center, WFIRM

Cynthia Wilkins-Port, PhD, MBA
Assoc. Dir. Process Dev., WFIRM

Lisa Hinshaw, MPH
Project Manager II, WFIRM

Darren Hickerson, MS, MDiv
Assist. Director, Manufacturing, WFIRM

Todd Meinecke, MBA
Asst. Director, Quality Assurance, WFIRM

Bioprinting Basics
John Jackson, PhD
Associate Professor, WFIRM

Carlos Kengla, PhD
Research Associate, WFIRM

Ashkan Shafiee, PhD
Post-Doctoral Fellow, WFIRM

Sang Jin Lee, PhD
Associate Professor, WFIRM

Peter Prim, PhD
Research Fellow, WFIRM

Bhushan Madadik, PhD
Research Associate, WFIRM

Anthony Melchoirri, PhD
Associate Director, Biomaterials Lab, Rice University

Body-on-a-Chip
Aleksander Skardal, PhD
Assistant Professor, WFIRM

Sean Murphy, PhD
Assistant Professor, WFIRM

Julio Aleman Hernandez
Research Lab Technician, WFIRM

Mahesh Devarasetty, PhD
Research Fellow, WFIRM

Andrea Mazzocchi
PhD Student, WFIRM

Hema Sivakumar
Research Lab Technician II, WFIRM

Riccardo Tamburrini, MD
Research Fellow, WFIRM

Goodwell Nzou
PhD Candidate, WFIRM

Timothy Leach
PhD Candidate, WFIRM

Shiny Rajan, PhD
Research Associate, WFIRM

Steven Forsythe, PhD
Postdoctoral Student, WFIRM

Oula Khoury
PhD Candidate, WFIRM

RME 2019 Career Perspectives Committee

James Poteracki
Pre-doctoral Fellow, WFIRM

Kelsey Willson
Pre-doctoral Fellow, WFIRM

Andrea Mazzocchi
Pre-doctoral Fellow, WFIRM

Adam Jorgensen
Pre-doctoral Fellow, WFIRM

Bradford Kuhlman
Pre-doctoral Fellow, WFIRM

WFIRM Lab Tours

James Yoo, MD, PhD
Assoc. Dir. & CSO, WFIRM

Tracy Criswell, PhD
Assistant Professor, WFIRM

Christopher Porada, PhD
Associate Professor, WFIRM

Sang Jin Lee, PhD
Associate Professor, WFIRM

Young Min Ju, PhD
Instructor, WFIRM

Aleksander Skardal, PhD
Assistant Professor, WFIRM

Colin Bishop, PhD
Professor, WFIRM

Kenneth Gyabaah
Imaging Core Technician, WFIRM

Ray Johnson
Lab Technician, WFIRM

Tara Jones
Genetics Core Technician, WFIRM

Cindy Zimmerman
Histology Core Technician, WFIRM

Other Contributors

Robert Harrison Bardsley IV
Research Lab Technician II, WFIRM

Terri Bowen,
Administrative Manager, WFIRM

Ernie Lookabill,
Financial Analyst WFIRM

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Important Information

RME 2019 Course Materials Dropbox link: **http://bit.ly/RME2019**

Registrants may also email Joan Schanck at jschanck@wakehealth.edu to request link be sent to them.

We're Social!

Like, follow, and connect with the Wake Forest Institute for Regenerative Medicine on social media. Follow along, post pictures, and ask questions by using the hashtag **#RMEssentials**. We will also post daily pictures from the course on our Facebook account.

@WFIRMnews **@WFIRMnews**

Wake Forest Institute for Regenerative Medicine

The RME Course has a mobile application utilizing the Yapp platform. The app contains the agenda, speaker information and much more. Visit https://my.yapp.us/ZG4BXZ on your mobile device to download.

Internet Access

Connect to IQGuest and accept terms.

Transportation

Complimentary transportation between WFIRM and Bowman Gray Center for Medical Education (CME) is provided by ABC Door2Door, adhering to the following schedule:

Monday, June 10th, 12:00 pm to 1:30 pm
From WFIRM (workshops) to Bowman Gray CME

Wednesday, June 12th, 3:45 pm to 6:00 pm
From Bowman Gray CME to WFIRM and return as needed

Friday, June 14th, 11:45 am to 1:00 pm
From Bowman Gray CME to WFIRM

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Visitor Information

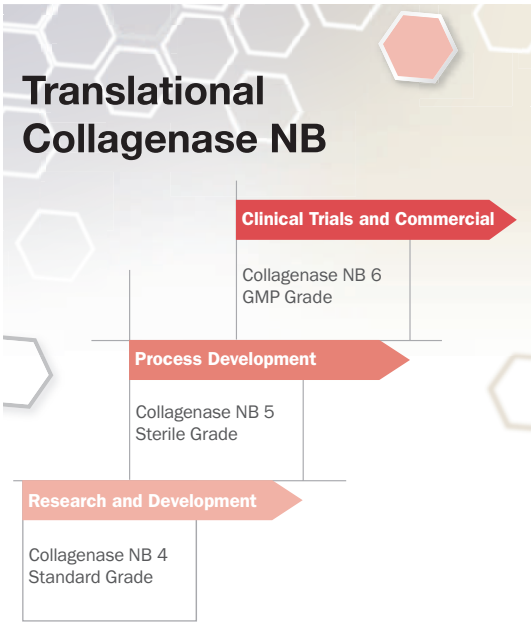
Course Venue: Bowman Gray Center for Medical Education

475 Vine Street
Winston-Salem, NC 27101

Bowman Gray Center for Medical Education

From the east (Greensboro):
Enter Winston-Salem on Business 40 West. Take exit 6C toward ML King Jr. Dr./Winston-Salem State University. Turn right onto ML King Jr. Dr. then left onto E. 3rd St. At the traffic circle, take the 1st exit onto N. Research Parkway. Turn left onto E. 4th St., turn right onto Vine St. then turn right onto E. 7th St. Parking lot P8 will be located on the right past Research Parkway. Follow path down E. 7th St. to turn left onto Vine St. to access the Bowman Gray Center for Medical Education.

From the west (Statesville):
Take I-40E to Winston-Salem. Keep left to take exit 193B for US-52N toward Mount Airy. Take the exit for S. Research Parkway and keep left at the fork to continue. At the traffic circle, take the 2nd exit onto N. Research Parkway. Turn right onto E. 4th St. Turn right onto Vine St. then turn right onto E. 7th St. Parking lot P8 will be located on the right past Research Parkway. Follow path down E. 7th St. to turn left onto Vine St. to access the Bowman Gray Center for Medical Education.



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Bowman Gray Center for Medical Education
FIFTH FLOOR

Hotels Near the Bowman Gray Center for Medical Education

- The Kimpton Cardinal Hotel
  336-724-5599
- Fairfield Inn & Suites
  336-714-2800
- Winston-Salem Marriott
  800-770-5675
- Embassy Suites by Hilton
  336-724-2300
- Hotel Indigo
  336-722-0720

Social Networking and Lab Tours: WFIRM

391 Technology Way
Winston-Salem, NC 27101

Wake Forest Institute for Regenerative Medicine

From the east (Greensboro): Enter Winston-Salem on Business 40 West. Take exit 6A to merge onto US 52 South. Take exit for Research Parkway and continue west. Turn left onto Rams Dr. and turn right onto E. Salem Ave. Turn left on Technology Way. Visitor parking is the first parking deck entrance on your right.

From the west (Statesville): Enter Winston-Salem on Business 40 East. Take exit 5A for Peters Creek Parkway and turn left. Continue onto Second Street, entering downtown. Turn right on Chestnut St. and turn left onto Technology Way. Visitor parking is the third parking deck entrance on your left.

Social Activities and Receptions

Monday, June 10
Evening Opening Reception - Bowman Gray CME 5th Floor
Heavy hors d'oeuvre with beer, wine and soda with California Fresh

Wednesday, June 12
Afternoon Reception - WFIRM
Lab tours and light hors d'oeuvre with beer and wine on the patio

Thursday, June 13
Southern Dinner Social - Bailey Park
Catered North Carolina BBQ and dessert with Sonny's BBQ

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Stay an Extra Day: Places to Visit

Old Salem Museums and Gardens
900 Old Salem Rd., Winston-Salem, NC
www.oldsalem.org
In the middle of bustling downtown Winston-Salem, you are steps away from the quieter place of the 18th-century Moravian village of Old Salem Museums and Gardens. Enjoy a self-guided walking tour of the historic town.


Old Salem

Reynolda House Museum of American Art
2250 Reynolda Rd., Winston-Salem, NC
www.reynoldahouse.org
The Reynolda House Museum of American Art holds a stellar collection of American art, decorative arts and costumes that transport visitors into the era of the early 20th century. Nearby Reynolda Village offers shops and restaurants.

Downtown Arts District & Shopping
400-700 Trade St., Winston-Salem, NC (and surrounding areas)
www.dadaws.org
Downtown/Trade Street District has restaurants, retail shops, residences, business offices, and more located in this eclectic area of downtown between 5th and 7th Streets on Trade Street. Many businesses are housed in historic buildings.

Stay an Extra Day: Places to Eat

The Tavern in Old Salem
736 South Main St.,
336-722-1227

Sweet Potatoes
529 Trade St.,
336-727-4844

Willow's Bistro
300 South Liberty Ct.,
336-293-460

Bib's Downtown
675 West 5th St.,
336-722-0007

Quanto Basta
680 West 4th St.,
336-893-6144

Krankies
211 East 3rd St.,
336-722-3016

Famous Toastery
770 Liberty View
336-306-9023


Tavern at Old Salem pecan pie


Quanto Basta roasted chicken

Course Instructors

Anthony Atala, MD
Director, Wake Forest Institute for Regenerative Medicine

Julie Allickson, PhD
Director, Regenerative Medicine Clinical Center, Wake Forest Institute for Regenerative Medicine

Graca Almeida-Porada, MD, PhD
Professor, Wake Forest Institute for Regenerative Medicine

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Tim Bertram, PhD
InReg/Twin City Bio

Andrew Breite, MS, MBA
Director, Quality Assurance, VitaCyte

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CEO and Board Chair, Javara Research

George Christ, PhD
Professor, Biomedical Engineering and Orthopaedic Surgery; Laboratory of Regenerative Therapeutics, University of Virginia

Abla Creasey, PhD
Vice President, Therapeutics and Strategic Infrastructure, FDA

Deborah Dorcemus, PhD
Field Application Scientist, Biological Industries USA

Jennifer Elisseeff, PhD
Wilmer Eye Institute and BME Translational Center, Johns Hopkins

John Fisher, PhD
Professor and Department Chair, University of Maryland; Director, NIH Center for Engineering Complex Tissues

Joshua Hare, MD, FACC, FAHA
Founding Director, Interdisciplinary Stem Cell Institute; Professor of Medicine, Molecular and Cellular Pharmacology, University of Miami

Faster Transition of New Therapies to Market

Delivering on the promise of regenerative medicine requires significant progress in manufacturing to scale up technologies and make them affordable.

Making this progress a reality is the focus of the Regenerative Medicine Development Organization (ReMDO) – a non-profit organization that manages a consortium of more than 60 industry and academic members. The ultimate goal is to accelerate the transition of regenerative medicine technologies to the global market.

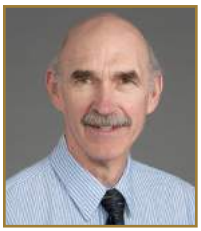
ReMDO
Advancing Regenerative Medicine Technologies

http://ReMDO.org

Brendan Harley, ScD
Professor, Department of Chemical & Biomolecular Engineering, Institute for Genomic Biology, University of Illinois at Urbana-Champaign

Ngan Huang, PhD
Assistant Professor, Department of Cardiothoracic Surgery, Stanford University

Joshua Hunsberger, PhD
Chief Technology Officer, RegenMed Development Organization (ReMDO); Executive Director, Regenerative Medicine Manufacturing Society (RMMS)



John Jackson, PhD
Associate Professor, Wake Forest Institute for Regenerative Medicine

Nancy King, JD
Professor, Social Sciences and Health Policy, Wake Forest School of Medicine; Professor, Wake Forest Institute for Regenerative Medicine; Co-Director, Center for Bioethics, Health and Society and Graduate Program in Bioethics, Wake Forest University

Douglas Losordo, MD
Executive Vice President, Global Head of Research and Development and CMO, Caladrius Biosciences

Frank Marini, PhD
Professor, Wake Forest Institute for Regenerative Medicine

Sean Murphy
Assistant Professor, Wake Forest Institute for Regenerative Medicine

Kiran Musunuru, MD, PhD, MPH, FAHA
Associate Professor, Cardiovascular Medicine and Genetics, Perelman School of Medicine, University of Pennsylvania

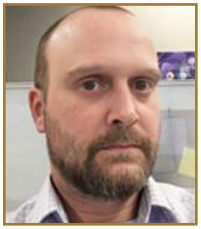
Laura Niklason, MD, PhD
Professor, Anesthesia and Biomedical Engineering, Yale University

Aletta Schnitzler, PhD
Head of Collaborations, Cell Therapy Bioprocessing

Aleksander Skardal, PhD
Assistant Professor, Wake Forest Institute for Regenerative Medicine

Bernard Siegel, JD
Executive Director, Regenerative Medicine Foundation

Gunes Uzer, PhD
Assistant Professor, Department of Mechanical and Biomedical Engineering, Boise State University

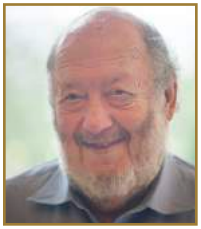


Gary Pigeau, PhD
Director, Center for Advanced Therapeutic Cell Technologies, GE Healthcare

Prajakta Varadkar, PhD
CMC Reviewer, Division of Cellular and Gene Therapies, FDA

Julie Watson, JD
Special Counsel, Marshall, Gerstein & Borun, LLP; Intellectual Property Director and Legal Counsel, WFIRM

Thomas Webster, PhD
Chair and Professor, Department of Chemical Engineering, Northeastern University



Irv Weissman, MD
Director, Stanford Institute for Stem Cell Biology and Regenerative Medicine; Ludwig Center for Center Stem Cell Research, Professor of Patholoy and Developmental Biology, Stanford University

David Williams, DSc
Professor and Director of International Affairs, Wake Forest Institute for Regenerative Medicine

James J. Yoo, MD, PhD
Associate Director, Wake Forest Institute for Regenerative Medicine

Agenda

Pre-Course Workshops: Monday, June 10th (concurrent)			
9:00am – 12:15pm	Workshop #1: Regenerative Medicine Enabling Technologies: Organoid/Body-on-a-Chip Engineering	Aleks Skardal, PhD and Sean Murphy, PhD WFIRM	
	Workshop #2: From Concept to Clinic: Introduction to Translation in Regenerative Medicine	Julie Allickson, PhD WFIRM	
	Workshop #3: 3D Bioprinting Basics for Regenerative Medicine	John Jackson, PhD, Sang Jin Lee, PhD and James Yoo, MD, PhD WFIRM	
Day 1: Monday, June 10th			
11:45am – 1:15pm	Arrival and Registration		5th Floor
1:15pm – 1:30pm	Welcome and Opening Remarks	Joan Schanck, MPA WFIRM	5107
	Session 1: Pluripotent Stem Cells and their Progenitors		
1:30pm – 2:15pm	*Introduction and Background: Current Concepts and Changing Trends*	Anthony Atala, MD WFIRM	5107
2:15pm – 3:00pm	*Normal and Neoplastic Stem Cells*	Irv Weissman, MD Stanford University	5107

3:00pm – 3:15pm	Refresh and Energize Break with Exhibitors		5th Floor
3:15pm – 4:00pm	*Stem Cells, Basic Biology, Therapeutic and Vehicles for Gene Delivery*	Graca Almeida-Porada, MD, PhD WFIRM	5107
4:00pm – 4:20pm	Panel and Attendees Discussion & Brief Closing Remarks	Chair: Dr. Almeida-Porada	5107
4:20pm – 6:00pm	Opening Reception (Heavy Hors D'oeuvres and Beer/Wine)		5th Floor
	Day 2: Tuesday, June 11th		
7:45am – 8:30am	Networking and Continental Breakfast		5th Floor
	Session 2: Biomaterials		
8:30am – 9:10am	*Essential Biomaterials Science*	David Williams, PhD, DSc WFIRM	5107
9:10am – 9:50am	*Engineering and Applications of Biomaterials in 3D Printing*	John Fisher, PhD University of Maryland/CECT	5107
9:50am – 10:10am	Refresh and Energize Break with Exhibitors		5th Floor
10:10am – 10:50am	*Engineering Porous Scaffolds for Regenerative Medicine*	Brendan Harley, DSc University of Illinois	5107
10:50am – 11:30am	*Engineering Naturally Derived Hydrogels for Biofabrication Applications*	Aleks Skardal, PhD WFIRM	5107

11:30am – 11:50am	Panel and Attendees Discussion	Chair: Dr. Williams	5107
11:50am – 1:15pm	Lunch Break and Exhibits		5206 (Seating 5203 & 5205)
11:50am – 1:15pm	Student-Mentor Luncheon Session I: Career Perspectives in Academia and the "Gray" Zone	James Poteracki and Kelsey Willson, WFIRM Pre-doctoral Fellows	5207
	Session 3: Enabling Technologies		
1:15pm – 1:55pm	*Bioprinting: Enabling Technology for Tissue Engineering & Regenerative Medicine*	John Jackson, PhD WFIRM	5107
1:55pm – 2:35pm	*Functional Imaging for Regenerative Medicine*	Frank Marini, PhD WFIRM	5107
2:35pm – 2:55pm	Refresh and Energize Break with Exhibitors		5th Floor
2:55pm – 3:35pm	*Nano Approaches in Regenerative Medicine*	Thomas Webster, PhD Northeastern University	5107
3:35pm – 4:15pm	*Genome Editing for Diagnostic and Therapeutic Applications*	Kiran Musunuru, MD, PhD, MPH University of Pennsylvania	5107
4:15pm – 4:40pm	Panel and Attendees Discussion	Chair: Dr. Jackson	5107
4:40pm – 6:00pm	Refresh and Energize Break with Exhibitors		5th Floor

Day 3: Wednesday, June 12th			
8:00am – 8:45am	Networking and Continental Breakfast		5th Floor
	Session 4: Cell Therapies		
8:45am – 9:25am	*Applications of Perinatal Stem Cells and Tissues*	Sean Murphy, PhD WFIRM	5107
9:25am – 10:05am	*Stem Cell Therapies for Human Heart Disease and Aging*	Joshua Hare, MD, FACC, FAHA University of Miami	5107
10:05am – 10:25am	Refresh and Energize Break with Exhibitors		5th Floor
10:25am – 11:05am	*The Microcirculation: Center of the Cardiovascular Repair Universe*	Douglas Losordo, MD, FACC, FAHA Caladrius Biosciences	5107
11:00am – 1:00pm	Regenerative Medicine Foundation Board Meeting	Bernie Siegel, JD + RMF Board	
11:05am – 11:30am	Panel and Attendees Discussion	Chair: Dr. Murphy	5107
11:30am – 1:00pm	Lunch Break and Exhibits		5206 (Seating 5203 & 5205)
11:30am – 12:45pm	Student-Mentor Luncheon Session II: Career Perspectives in Industry	Andrea Mazzocchi, Adam Jorgensen and Bradford Kuhlman, WFIRM Pre-doctoral Fellows	5207

12:45pm – 12:55pm	Biological Industries Presentation with Discussion 	Deborah Dorcemus, PhD Biological Industries	5107
	Session 5: Tissue Engineered Products & Technologies (TEMPs)		
1:00pm – 1:40pm	*Considerations for Developing Tissue Engineered & Regenerative Medicine Products*	James Yoo, MD, PhD WFIRM	5107
1:40pm – 2:20pm	*Engineering Functional Complex Tissues*	Laura Niklason, PhD Yale University	5107
2:20pm – 2:40pm	Refresh and Energize Break with Exhibitors		5th Floor
2:40pm – 3:20pm	*Regenerative Medicine Translation and New Directions in Immunotherapies*	Jennifer Elisseeff, PhD Johns Hopkins	5107
3:20pm – 3:35pm	Panel and Attendees Discussion	Chair: Dr. Yoo	5107
3:35pm – 4:00pm	Refresh and Energize Break with Exhibitors		5th Floor
4:30pm – 5:15pm	WFIRM "Into the Lab" Tours (Shuttle Service to WFIRM from Course Venue begins 3:45pm)	Tours begin at 4:30pm	
5:00pm – 6:30pm	Social Networking with Refreshments (Light Hors D'oeurves and Beer/Wine)		Outdoor patio at WFIRM

1:00pm – 1:40pm	*Considerations for Developing Tissue Engineered & Regenerative Medicine Products*	James Yoo, MD, PhD WFIRM	5107
1:40pm – 2:20pm	*Engineering Functional Complex Tissues*	Laura Niklason, PhD Yale University	5107
2:20pm – 2:40pm	Refresh and Energize Break with Exhibitors		5th Floor
2:40pm – 3:20pm	*Regenerative Medicine Translation and New Directions in Immunotherapies*	Jennifer Elisseeff, PhD Johns Hopkins	5107
3:20pm – 3:35pm	Panel and Attendees Discussion	Chair: Dr. Yoo	5107
3:35pm – 4:00pm	Refresh and Energize Break with Exhibitors		5th Floor
4:30pm – 5:15pm	WFIRM "Into the Lab" Tours (Shuttle Service to WFIRM from Course Venue begins 3:45pm)	Tours begin at 4:30pm	
5:00pm – 6:30pm	Social Networking with Refreshments (Light Hors D'oeurves and Beer/Wine)		Outdoor patio at WFIRM
	Day 4: Thursday, June 13th		
7:45am – 8:25am	Networking and Continental Breakfast		5th Floor
	Session 6: Regulatory, Process Development & Biofabrication/Manufacturing		

1:00pm – 1:40pm	*Considerations for Developing Tissue Engineered & Regenerative Medicine Products*	James Yoo, MD, PhD WFIRM	5107
1:40pm – 2:20pm	*Engineering Functional Complex Tissues*	Laura Niklason, PhD Yale University	5107
2:20pm – 2:40pm	Refresh and Energize Break with Exhibitors		5th Floor
2:40pm – 3:20pm	*Regenerative Medicine Translation and New Directions in Immunotherapies*	Jennifer Elisseeff, PhD Johns Hopkins	5107
3:20pm – 3:35pm	Panel and Attendees Discussion	Chair: Dr. Yoo	5107
3:35pm – 4:00pm	Refresh and Energize Break with Exhibitors		5th Floor
4:30pm – 5:15pm	WFIRM "Into the Lab" Tours (Shuttle Service to WFIRM from Course Venue begins 3:45pm)	Tours begin at 4:30pm	
5:00pm – 6:30pm	Social Networking with Refreshments (Light Hors D'oeurves and Beer/Wine)		Outdoor patio at WFIRM
	Day 4: Thursday, June 13th		
7:45am – 8:25am	Networking and Continental Breakfast		5th Floor

Session 6: Regulatory, Process Development & Biofabrication/Manufacturing			
8:25am – 9:05am	*Translational Research from Proof-of-Concept to Clinical Trials*	Julie Allickson, PhD WFIRM	5107
9:05am – 9:45am	*Manufacturing Challenges*	Joshua Hunsberger, PhD Regenerative Medicine Manufacturing Society	5107
9:45am – 10:25am	*Regulatory Considerations for Development of Cell-Based Products*	Prajakta Varadkar, PhD FDA	5107
10:25am – 10:45am	Refresh and Energize Break with Exhibitors		5th Floor
10:45am – 11:25am	*GE Healthcare: Cell and Gene Therapy Strategy*	Gary Pigeau, PhD GE Healthcare	5107
11:25am – 11:40am	Panel and Attendees Discussion	Chair: Dr. Allickson	5107
11:40am – 1:10pm	Lunch Break and Exhibits		5206 (Seating 5203 & 5205)
12:55pm – 1:05pm	Vitacyte Presentation with Discussion 	Andrew Breite, PhD Vitacyte	5107
Session 7: Clinical Trials & Bioethics			

1:10pm – 1:40pm	*RegenMed: The New Disruptor in the World of Clinical Trials*	Jennifer Byrne Javara	5107
1:40pm – 2:20pm	*Accelerating Regenerative Medicine to the Clinics through the CIRM Partnership Model*	Abla Creasy, PhD California Institute of Regenerative Medicine (CIRM)	5107
2:20pm – 2:40pm	Refresh and Energize Break with Exhibitors		5th Floor
2:40pm – 3:10pm	*Research Ethics for Regenerative Medicine: Both Fundamental and Creative*	Nancy M. P. King, JD Wake Forest School of Medicine	5107
3:10pm – 3:40pm	Panel and Attendees Discussion	Chair: Nancy King	5107
3:40pm – 4:00pm	Refresh and Energize Break with Exhibitors		5th Floor
	Session 8: Regenerative Rehabilitation		
4:00pm – 4:35pm	*Overview and New Directions in Regenerative Rehabilitation: Modeling and Biomechanics for Improved Mechanistic Insight into Volumetric Muscle Loss Injury and Repair*	George Christ, PhD University of Virginia	5107
4:35pm – 5:10pm	*Harnessing Nuclear Envelope Mechanobiology of Stem Cells for Regenerative Therapies*	Gunes Uzer, PhD Boise State University	5107
5:10pm – 5:45pm	*Skeletal Muscle Tissue Engineering and Regenerative Rehabilitation*	Ngan Huang, PhD, FAHA Stanford Cardiovascular Institute	5107

2:40pm – 3:10pm	*Research Ethics for Regenerative Medicine: Both Fundamental and Creative*	Nancy M. P. King, JD Wake Forest School of Medicine	5107
3:10pm – 3:40pm	Panel and Attendees Discussion	Chair: Nancy King	5107
3:40pm – 4:00pm	Refresh and Energize Break with Exhibitors		5th Floor
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5:10pm – 5:45pm	*Skeletal Muscle Tissue Engineering and Regenerative Rehabilitation*	Ngan Huang, PhD, FAHA Stanford Cardiovascular Institute	5107
5:45pm – 6:00pm	Panel and Attendees Discussion	Chair: Dr. Christ	5107
6:00pm – 7:15pm	North Carolina BBQ and Social Networking		Bailey Park, across from Bowman Gray
	Day 5: Friday, June 14th		
8:00am – 8:45am	Networking and Continental Breakfast		5th Floor

	Session 9: Commercialization		
8:45am – 9:30am	*IP 101: Securing IP for Regenerative Medicine*	Julie Watson, JD WFIRM	5107
9:30am – 9:50am	Coffee Break		5th Floor
9:50am – 10:30am	*Toward Commercialization: Considerations for Product and Process Development*	Aletta Schnitzler, PhD MilliporeSigma	5107
10:30am – 11:10am	*Commercial Planning of a Biotechnology Product - The Industry, Company, People and Product*	Tim Bertram, PhD InRegen/Twin City Bio	5107
11:10am – 11:30am	*Panel and Attendees Discussion*	Moderator: Bernie Siegel, JD Regenerative Medicine Foundation	5107
11:30am – 11:45am	Wrap-Up and Concluding Remarks	Joan Schanck, MPA WFIRM	5107
	Post-Course Workshop: Friday, June 14th (concurrent)		
11:45am – 1:15pm	Workshop #1: Regenerative Medicine Enabling Technologies: Organoid/Body-on-a-Chip Engineering	Aleks Skardal, PhD and Sean Murphy, PhD WFIRM	
	Workshop #3: 3D Bioprinting Basics for Regenerative Medicine	John Jackson, PhD, Sang Jin Lee, PhD and James Yoo, MD, PhD WFIRM